

**Notice of Allowability**

Application No.

09/724,000

Examiner

Stephen L. Rawlings, Ph.D.

Applicant(s)

POLVERINO ET AL.

Art Unit

1643

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 08 August 2007.
2. ☒ The allowed claim(s) is/are 9, 13, 14, 16, 46, 47, 57, 59-61, 63 and 64.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20070823.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

/Stephen L. Rawlings/  
Stephen L. Rawlings, Ph.D.  
Primary Examiner, Art Unit 1643

### EXAMINER'S AMENDMENT

1. The amendment filed August 8, 2007, is acknowledged and has been entered. Claims 13, 16, 57, and 61 have been amended.
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.
3. Authorization for this examiner's amendment was given in a telephone interview with Isadora F. Bielsky, Ph.D., on August 23, 2007.
4. The application has been amended as follows:

In the claims:

The following set of claims has replaced the prior set of claims submitted as part of the amendment filed August 8, 2007:

Claims 1-8. (Cancelled)

Claim 9. (Previously Presented) An isolated polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5 produced by a process comprising: (a) culturing a host cell containing a vector comprising a nucleic acid having a nucleotide sequence: (i) as set forth in SEQ ID NO. 4; (ii) of a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755; or (iii) encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO. 5; under conditions suitable to express the polypeptide; and optionally (b) isolating the polypeptide from the culture.

Claims 10-12. (Cancelled)

Claim 13. (Previously Presented) An isolated polypeptide comprising the amino acid sequence: (a) as set forth in SEQ ID NO: 5; or (b) encoded by a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755, wherein the DNA insert encodes a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5.

Claim 14. (Currently Amended) An isolated polypeptide ~~comprising~~ consisting of: (a) the amino acid sequence as set forth in SEQ ID NO: 6, optionally further comprising an amino-terminal methionine; or (b) the amino acid sequence as set forth in SEQ ID NO: 6 and an amino-terminal methionine.

Claim 15. (Cancelled)

Claim 16. (Previously Presented) An isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5 encoded by a nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of: (a) the nucleotide sequence as set forth in SEQ ID NO: 4; (b) the nucleotide sequence of a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755, wherein the DNA insert encodes a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5; and (c) a nucleotide sequence encoding a polypeptide having an the amino acid sequence as set forth in SEQ ID NO: 5.

Claims 17-45. (Cancelled)

Claim 46. (Currently Amended) An isolated fusion polypeptide comprising the

polypeptide of either Claim 13 or 14 fused to a heterologous amino acid sequence.

Claim 47. (Previously Presented) The isolated fusion polypeptide of Claim 46, wherein the heterologous amino acid sequence is an IgG constant domain or fragment thereof.

Claims 48-56. (Cancelled)

Claim 57. (Previously Presented) A polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5 produced by a process comprising (a) culturing a host cell containing a vector comprising a nucleic acid molecule having a nucleotide sequence of a region of the nucleotide sequence of: (i) SEQ ID NO: 4; or (ii) a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755, under suitable conditions to express the polypeptide; and optionally (b) isolating the polypeptide from the culture.

Claim 58. (Cancelled)

Claim 59. (Previously presented) The polypeptide of either Claim 9 or 57, wherein the host cell is a eukaryotic cell.

Claim 60. (Previously presented) The polypeptide of either Claim 9 or 57, wherein the host cell is a prokaryotic cell.

Claim 61. (Previously Presented) An isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5 encoded by a nucleic acid molecule comprising a nucleotide sequence of a region of the nucleotide sequence of: (a) SEQ ID NO: 4; or (b) a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755.

Claim 62. (Cancelled)

Claim 63. (New) An isolated fusion polypeptide comprising the polypeptide of claim 14 fused to a heterologous amino acid sequence.

Claim 64. (New) The isolated fusion polypeptide of claim 63, wherein the heterologous amino acid sequence is an IgG constant domain or fragment thereof.

***Examiner's Statement of Reasons for Allowance***

5. The following is an examiner's statement of reasons for allowance:

Applicant's amendment filed August 8, 2007, has obviated or rendered moot the grounds of rejection under 35 U.S.C. § 112, first and/or second paragraph, of claims 13, 14, 16, 46, 47, 57, and 59-61, which are set forth in the preceding Office action mailed May 8, 2007.

Notably, claim 14 was inadvertently listed in the rejection of claims under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. As explained at page 12, paragraph 2, of the Office action mailed May 8, 2007, claim 14 was not rejected because there is a reasonable presumption that the claimed polypeptide will have or retain the function of a full-length polypeptide comprising the amino acid sequence of SEQ ID NO: 5. This is because the polypeptide of SEQ ID NO: 6 is described as the mature form of the polypeptide of SEQ ID NO: 5, which lacks the leader sequence (i.e., the secretory signal sequence of which the full-length polypeptide of SEQ ID NO: 5 is comprised); and the Examiner finds no factual evidence teaching or reasonably suggesting that such a polypeptide would not do so. See *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) ("[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance

with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.")

Additionally, the supplemental declaration under 37 C.F.R. § 1.131 by Anthony J. Polverino, which was filed August 8, 2007, is sufficient to overcome the rejection of claims 9, 13, 16, 57, and 59-61 based upon U.S. Patent Application Publication No. 2002/0068319 A1.

Finally, with regard to claims 14, 63, and 64, the prior art does not teach or fairly suggest a polypeptide consisting of the amino acid sequence of SEQ ID NO: 6.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

7. Claims 9, 13, 14, 16, 46, 47, 57, 59-61, 63, and 64 have been allowed.

8. Claims 9, 13, 14, 16, 46, 47, 57, 59-61, 63, and 64 have been renumbered as claims 1-12, respectively.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen L. Rawlings/  
Stephen L. Rawlings, Ph.D.  
Primary Examiner  
Art Unit 1643

slr  
August 23, 2007